510(k) Summary Pursuant to 21 CFR 807.92

FEB - 6 2014

DATE: December 23, 2013 **K132824**

1.	Submitted By:	Carestream Health, Inc. 150 Verona Street Rochester, NY 14608
2.	Contact:	David C. Furr Becker & Associates Consulting, Inc. 8708 Capehart Cove Austin, Texas 78733 512-906-9654
3.	Product:	CARESTREAM Vue PACS Regulation – 892.2050 Classification - II Product Code: LLZ
4.	Common/Trade Name:	Picture archiving and communications system CARESTREAM Vue PACS v11.4 Vue Motion

Description:

CARESTREAM Vue PACS is an image management system whose intended use is to provide completely scalable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems.

It is a software only solution that contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates the review, dictation and reporting tools that creates a productive work environment for the radiologists and physicians.

Vue PACS provides functionality to allow remote site access to image and patient data enabling diagnostic reading through industry standard interfaces. It is designed using an open architecture that allows for various proprietary and off the shelf software components to be integrated with off the shelf hardware components and configured meeting the user's specific needs in a single-site or multi-site environment.

CARESTREAM Vue Motion is a Light Viewer designed to provide wireless and portable access to medical images for remote reading or referral purposes from web browsers including enterprise distribution of the radiology images and related data. The needs to provide real time imaging results and imaging related data to the enterprise

users' commands that imaging solutions have a simple distribution mechanism through simple and broadly used technology. The patient portfolio is made available to physicians from their offices within their EMR, from home on local PC's or remotely through tablet and other devices. With integration into EMR systems, Vue Motion helps hospital users and healthcare facilities enhance patient care, by bringing the complete patient imaging record and supporting data into the healthcare enterprise. Image storage, viewing and distribution becomes a seamless part of the EMR.

A "patient search page", including smart Google-like search capabilities is also available for users that have no local EMR/HIS integration.

Vue Motion is offered as an option for the PACS, Vue Archive (onsite or via Vue Cloud) or The Carestream Vendor Neutral Archive and provides a zero footprint imaging viewer that can be deployed on the fly and accessible by the right user from anywhere, over virtually any operating system or over virtually any browser enabled device. The software technology uses HTML5 which allows any browser enabled device to run the software application.

CARESTREAM Vue Motion has a simpler GUI for viewing including zoom, pan, windowing, basic measurements, cine etc. It works on any operating system and with virtually any browser enabled device such as PC's, iPad, mobiles etc. It is self-deployable and performs well over low bandwidth networks. It supports collaboration with other users through the sticky notes mechanism.

Intended Use:

The CARESTREAM Vue PACS is an image management system whose intended use is to provide completely scalable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems.

The system contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates review, dictation and reporting tools to create a productive work environment for the radiologists and physicians.

The Vue Motion software program is used for patient management by clinicians in order to access and display patient data, medical reports, and medical images for diagnosis from different modalities including CR, DR, CT, MR, NM and US.

Vue Motion provides wireless and portable access to medical images for remote reading or referral purposes from web browsers including usage with validated mobile devices. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. For primary interpretation and review of mammography images, only use display hardware that is specifically designed for and cleared by the FDA for mammography.

Technological Characteristics:

CARESTREAM Vue PACS v11.4 Vue Motion is fully compatible with CARESTREAM PACS and can be displayed on additional devices. The software is only intended for the iPad 2, iPhone 4S, Galaxy S3, and Galaxy Note 10.1 or newer versions with equal or better performance.

The product is software, and has been extensively tested in accordance with *General Principles of Software Validation; Final Guidance for Industry and FDA Staff.* The product is DICOM Compliant.

Clinical and Non-Clinical Testing included the following:

- Bench Testing was done on each the Apple iPad2, Apple iPhone 4S, Galaxy S3, and Galaxy Note 10.1 for performance in Luminance Response, Device and Display Settings, Optimal Viewing Angle, Resolution, Noise, Reflectivity, Battery Life, and Exception Handling.
    - Each of the devices was determined to be acceptable in the bench performance testing and the results support equivalence to the Carestream PACS predicate.

- Clinical Assessments of Vue Motion were performed on the Apple iPad2, Apple iPhone 4S, Samsung Galaxy SIII, and Samsung Galaxy Note 10.1.
    - The Clinical Assessments indicated that Vue Motion images of diagnostic quality can be displayed on each of the devices across all target modalities. The Clinical Assessments support equivalence to the Carestream PACS predicate.

- Functional QA testing of the software on PCs, Mobile and Tablet Devices was performed to demonstrate that key features of the system operate acceptably.

Substantial Equivalence:

CARESTREAM Vue PACS v11.4 Vue Motion is next generation software based on the CARESTREAM PACS (K110919). The new product brings the features of the CARESTREAM PACS predicate to additional display devices such as mobile phones and tablets. It performs the same and the new mobile and tablet devices have been demonstrated to be suitable as a platform for image display. No substantial differences that affect safety and efficacy were noted.

Conclusion:

CARESTREAM Vue PACS v11.4 Vue Motion is substantially equivalent to the CARESTREAM PACS predicate. It has been extensively validated and tested and no substantial differences that affect safety and efficacy were noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2014

Carestream Health, Inc.
% Mr. David C. Furr
Regulatory Representative
Becker & Associates Consulting, Inc.
8708 Capehart Cove
AUSTIN TX 78733

Re: K132824
Trade/Device Name: Carestream Vue PACS (Version 11.4 Carestream Vue Motion Application)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 23, 2013
Received: December 26, 2013

Dear Mr. Furr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

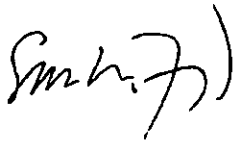
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132824

Device Name
CARESTREAM Vue PACS v11.4

Indications for Use *(Describe)*

The CARESTREAM Vue PACS is an image management system whose intended use is to provide completely scalable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems.

The system contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates review, dictation and reporting tools to create a productive work environment for the radiologists and physicians.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*